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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/295,663 | JOSHI ET AL. | |
| | Examiner | Art Unit | |
| | Joseph T. Woitach | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after final filed August 25, 2003.
2. ☒ The allowed claim(s) is/are 38-44, 46-48, 50, 51, 69-79 and 82-87.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

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DETAILED ACTION

This application, filed April 21, 1999, claims benefit to provisional applications: 60/082,665 filed April 22, 1998, 60/111,635 filed December 9, 1998, and 60/11,637 filed December 9, 1998.

Applicants' amendment filed August 25, 2003 has been received and entered. Claims 49, 80 and 81 have been canceled. Claims 38, 42, 69, 71-73 and 82 have been amended. Claims 38-44, 46-48, 50, 51, 69-79, 82-87 are pending and currently under examination.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The amendment to claim 42 has obviated the objection the claim. The amendments to independent claims 38 and 69 has differentiated the claimed invention from that disclosed by Son *et al.* and obviated the basis of the rejection of claims 38-44, 47, 48, 50, 69-73, 79 and 84-86 made under 35 U.S.C. 102(b). With respect to the rejection of claims 38-44, 47, 48, 50, 69-73 and 78, 79, 82-86 under 35 U.S.C. 103(a) as being unpatentable over Roth *et al.*, Son *et al.* and Walker *et al.*, and claims 74-77 and 87 under 35 U.S.C. 103(a) as being unpatentable over Roth *et al.*, Son *et al.* and Bally *et al.* Applicants argue that in light of the new claim amendments and in view of the lack of success for the specific cell cycle blocking agents taught in Roth *et al.* recited and encompassed by the claims, there would be no motivation or expectation of success

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to combine the teachings of Walker *et al.*, Son *et al.* and Bally *et al.* for the specific lipid formulations. Examiner agrees that the teaching of Roth *et al.* would not lead one to expect that the agents cyclophosphamide, taxol, taxolene or a vinca alkaloid could be combined with the delivery systems taught in Walker *et al.*, Son *et al.* and Bally *et al.* to provide for a successful method of introducing a nucleic acid sequence into a cell of a patient. The lack of success provided in the teaching of Roth *et al.* would not provide the motivation or expectation of success provided in the instant disclosure for the particular combination of cell cycle blockers and lipid formulations encompassed by the instant claims.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600